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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,390

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Harold N. Trick

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04/17/2008

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

04/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,390	Applicant(s) TRICK ET AL.	
	Examiner MEDINA A. IBRAHIM	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,14-23,26,29-38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 7-8, 14, 21-22, 37, and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,15-20,23,26,29-36,38,40 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 23, 26 and 42 are amended. Claims 27-28 are cancelled. Therefore, 1, 7-9, 14-23, 26, 29-38, and 40-42 are pending. Claims 7-8, 14, 21-22, 37, and 41 are withdrawn from consideration as being directed to the non-elected invention.

Claims 1, 9, 15-20, 23, 26, 29-36, 38, 40, and 42 are under examination.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment to the claims and/or upon further consideration.

Claim Rejections - 35 USC § 112

Claims 1, 9, 15-20, 23, 26, 29-36, 38, 40, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 09/18/07. Applicant's arguments filed 01/17/08 have been fully considered but are not deemed persuasive.

Applicant reiterates that the specification provides sequences corresponding to *H. glycines* embryonic lethal phenotype genes that fall within the scope of the claims and Examples for methods of cloning such genes from *H. glycines*. Applicant refers to Table 1 (pp. 35-37) and Examples 1-3 of the specification. Applicant asserts that the

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structure and function of said sequences are described by the specification. Applicant argues that one of skill in the art would be able to either use the identified genes or clone additional genes that fall within the scope of the genes from *H. glycines* and use them as exemplified in the instant specification (response, pp. 9-10).

These are not found persuasive for three main reasons: firstly, Table 1 of the specification describes subsequences for *H. glycines* major sperm protein gene (SEQ ID NO: 1), RNA polymerase II gene (SEQ ID NO: 18), and chitin synthase gene (SEQ ID NO: 9), rather than *H. glycine* embryonic lethal phenotype genes. Neither the specification nor the prior art identifies the major sperm protein gene, RNA polymerase II gene, and chitin synthase gene as embryonic lethal phenotype genes. In fact, the specification provides no description regarding the composition and structure of an embryonic lethal phenotype gene. Secondly, transgenic plants expressing dsRNA from SEQ ID NO: 1 for use in RNAi to produce nematode resistant transgenic plants are not rejected. Thirdly, neither the instant specification nor the prior art describes a structural element specific to all *H. glycine* embryonic lethal phenotype genes that define function essential for embryonic survival of the nematode, which would allow one to predictably determine the identity of the members of genus of the nucleic acids as encompassed in the instant claims. In addition, even if SEQ ID NO: 1, 9 and 18 are considered to be embryonic lethal phenotype genes, they are not representative sample, given that the genus is large and encompasses genes yet to be identified for lethality. Therefore, absent representative number of *H. glycine* embryonic lethal phenotype genes having RNAi function, the claimed invention lacks adequate written description.

In addition, Applicant's arguments that one of skill in the art would be able to either use the identified genes or clone additional genes that fall within the scope of the genes from *H. glycines* and use them as exemplified in the instant specification are enablement issues rather than written description issues. The instant claims are rejected for lack of written description and not for lack of enablement. The Written description requirement is separate and apart from the enablement requirement and conclusive evidence of claim's enablement is not equally conclusive of that claim's satisfactory written description. See, for example, *In re Curtis*, 69 USPQ2d 1274 (Fed. Cir. 2004), and *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (Fed. Cir. 2004).

Applicant cites the decision by Federal Circuit in *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005), asserting that the situation of the instant application is more pertinent to *Capon* rather than to that of *Eli Lilly*.

This is not found persuasive because, in *Capon*, the specification provided specific examples of genes within the scope of the claims and how to identify and isolate other genes useful in the claimed invention. In the instant application, the specification exemplified a single gene for use in RNAi, the soybean major sperm protein, which is not a representative sample of the genus of *H. glycines* embryonic lethal phenotype genes including genes yet to be discovered and/or characterized. Also, unlike the instant claims, the chimeric genes claimed in *Moba* were produced by selecting and combining known heavy and light chain immune related DNA sequences. The structure and properties of the DNA components were known.

Therefore, for all the reason discussed above and in the last Office action, The claimed invention is not adequately described.

An amendment to the claims to the recite specific embryonic lethal phenotype genes sequences or subsequences would obviate the above rejection.

Remarks

The claims are free of the prior art of record.

No claim is allowed.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0795.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/10/08

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638

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